REMARKS

Claim 19 is pending in the subject application. Applicants have amended claim 19. Accordingly, upon entry of this Amendment, claim 19 will still be pending and under examination.

Applicants maintain that the amendments to claim 19 do not raise any issue of new matter, and that this claim as amended is fully supported by the specification as originally filed. Accordingly, applicants respectfully request that this Amendment be entered.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the December 30, 2003 Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

Claimed Invention

This invention provides a substantially purified extracellular domain of the human neu gene product, said extracellular domain being detectable in a biological fluid by its immunoreactivity with a monoclonal antibody or immunoreactive fragment thereof produced by the hybridoma cell line OD-3, NB-3 or TA-1.

Rejection Under 35 U.S.C. §112, Second Paragraph - Indefiniteness

The Examiner rejected claim 19 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner asserts that claim 19 is indefinite because it contains the phrase "said product", which lacks antecedent basis in the claim.

In response, applicants point out that amended claim 19 does not recite "said product", and therefore, the rejection is obviated.

In view of the above remarks, applicants maintain that amended claim 19 satisfies the requirements of 35 U.S.C. §112, second paragraph.

Rejection Under 35 U.S.C. §102(e)

The Examiner rejected claim 19 under 35 U.S.C. §102(e) as allegedly anticipated by Hudziak et al. (U.S. Patent No. 6,015,567, "Hudziak") or Ring et al. (U.S. Patent No. 6,054,561; "Ring").

In response, applicants respectfully traverse.

Again, claim 19 provides a substantially purified extracellular domain of the human neu gene product, said extracellular domain being detectable in a biological fluid by its immunoreactivity with a monoclonal antibody or immunoreactive fragment thereof produced by the hybridoma cell line OD-3, NB-3 or TA-1.

Under 35 U.S.C. §102(e), and as stated in M.P.E.P. §2131.01, "[a] claim is anticipated only if *each and every element* as set forth in the claim is found, either

expressly or inherently described, in a single prior art reference." (emphasis added). Hence, to anticipate the method of claim 19, Hudziak and Ring would each have to teach each and every element thereof.

Hudziak and Ring fail to do this.

Hudziak teaches an extracellular domain of human HER2 molecule that can be used to provoke a cell-mediated immune response to HER2 molecule in a patient treated therewith. Nowhere does Hudziak teach that the extracellular domain of human neu molecule is detectable in a biological fluid by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof. Hudziak also does not teach that the extracellular domain of human neu molecule is detectable in a biological fluid at all. Hence, Hudziak fails to teach each and every element of the rejected claim.

Ring teaches a breast cancer-specific antibody designated 520C9 that binds to an approximately *200kD* protein identified as "c-erbB-2." Ring does not teach a substantially purified *extracellular domain* of the human neu gene product which, as stated on page 6 of the specification, has a molecular weight of about *97 to 115kD*. Furthermore, Ring does not teach that the extracellular domain of human neu gene product is detectable in a biological fluid by its immunoreactivity with a monoclonal antibody or immunoreactive fragment thereof produced by the hybridoma cell line OD-3, NB-3 or TA-1.

Ring also teaches another breast cancer-specific antibody designated 113F1 that binds to a number of *diffuse* bands with approximate molecular weights ranging from 40-200kD. The applicants respectfully disagree with the Examiner's assertion that the antigens disclosed in Ring, i.e., those ranging from 40-200kD, read on applicants' range. The only antigen that falls within the range stated on page 6 of the specification, i.e., about 97 to 115kD, is a *diffuse* band with an approximate molecular weight of 100kD which is recognized by the 113F1 antibody. Ring does not teach that the 113F1 antibody binds to the extracellular domain of the human neu gene product, nor even the "200kD protein identified as c-erbB-2" disclosed in the reference. Furthermore, nowhere in Ring is it disclosed that the diffuse 100kD band is the extracellular domain of the human neu gene product. Rather, as stated in column 27, lines 22-24 of Ring, the 100kD band is one of a number of bands which "are suspected to be one *or more* glycoproteins bearing the same or similar carbohydrates." Hence, Ring fails to teach each and every element of the rejected claims.

Therefore, neither Hudziak nor Ring teaches each and every element of claim 19, as amended, and therefore, claim 19 is novel over each of these references.

In view of the above remarks, applicants maintain that claim 19 satisfies the requirements of 35 U.S.C. §102(e).

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claim 19 under 35 U.S.C. §102(b) as allegedly anticipated by Yamamoto (Nature, 319: 230-234, 1986) or Coussens (Science, 230:1132-1139, 1985).

In response, applicants respectfully traverse.

Again, claim 19 provides a substantially purified extracellular domain of the human neu gene product, said extracellular domain being detectable in a biological fluid by its immunoreactivity with a monoclonal antibody or immunoreactive fragment thereof produced by the hybridoma cell line OD-3, NB-3 or TA-1.

Under 35 U.S.C. §102(b), and as stated in M.P.E.P. §2131.01, "[a] claim is anticipated only if *each and every element* as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added). Hence, to anticipate the methods of claim 19, Yamamoto and Coussens would each have to teach each and every element thereof.

Yamamoto and Coussens fail to do this.

Yamamoto teaches a polypeptide and its extracellular domain encoded by the human c-erb-B-2 gene. However, Yamamoto does not teach that the polypeptide, let alone its extracellular domain, is detectable in a biological fluid by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof. In fact,

Yamamoto does not teach that the polypeptide or its extracellular domain is detectable in a biological fluid at all. Hence, Yamamoto fails to teach each and every element of the rejected claim.

Coussens also shares the same deficiencies as Yamamoto. Coussens teaches a human neu oncogene product and its extracellular domain. However, Coussens does not teach that the oncogene product, let alone its extracellular domain, is detectable in a biological fluid by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof. Like Yamamoto, Coussens also does not teach that the oncogene product or its extracellular domain is detectable in a biological fluid. Coussens therefore also fails to teach each and every element of the rejected claim.

In view of the above remarks, applicants maintain that claim 19 satisfies the requirements of 35 U.S.C. §102(b).

Summary

Applicants maintain that pending claim 19 is in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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